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K021630
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Section 5 Summary of Safety and Effectiveness

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

5.1 General Provisions

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, Minnesota 55311
Contact Person	Todd Kornmann (763) 494-2467
Classification Name	Biliary Catheter and Accessories Product Code – 78 FGE Regulation Number 21 CFR Part 876.5010
Common or Usual Name	Biliary Stent and Balloon Dilatation Catheter
Proprietary Name	Boston Scientific Corporation Express Biliary LD Premounted Stent System

5.2 Name of Predicate Devices

Boston Scientific Ultra-thin™ SDS Balloon Dilatation Catheter and Johnson & Johnson Corinthian™ IQ Transhepatic Biliary Stent

5.3 Device Description

Stent

The Express Biliary LD stent will be substantially equivalent to the legally marketed Johnson & Johnson Corinthian IQ Transhepatic Biliary Stent (K992755).

The Express Biliary LD Stent is a balloon expandable metallic stent intended to maintain patency of biliary strictures produced by malignant neoplasms. The stent will be available in a variety of sizes to address clinician needs.

The Express Biliary LD Stent is made from 316L surgical grade stainless steel tubing. The seamless tubing is initially extruded to a cylindrical shape, and is then drawn down in a series of steps to the final tubing dimension. The stent is formed by laser cutting the

pattern from the tube, after which it is cleaned and electropolished to obtain smooth rounded struts.

The geometry is a continuous pattern consisting of large and small sinusoidal bands connected by axial struts. The deployed stent provides excellent radial strength while conforming to the natural curvature of the anatomy. The stent provides a ghost like image using conventional radiographic imaging equipment.

The Express Biliary LD Stent will be offered in Small Vessel (SV) and Large Vessel (LV) models. The SV model will be used for vessel diameters ranging from 6 mm through 8 mm, with lengths of 17 mm, 37 mm, and 57 mm. The LV model will be used for vessel diameters of 9 mm and 10 mm with lengths of 25 mm, 37 mm, and 57 mm.

Delivery Catheter

The Express Biliary LD balloon delivery catheter will be substantially equivalent to the legally marketed Boston Scientific Ultra-thin SDS Balloon Dilatation Catheter (K011889 and K011909). The delivery catheter is identical to the predicate catheter with the exception of one minor component and material change and one design change associated with the number of balloon folds. The hub utilized for the delivery catheter will be the hub design currently used on the Boston Scientific Synergy Balloon Dilatation Catheter (submitted under the name SC 35 Balloon Dilatation Catheter), cleared to market under K993303 and K993305.

The Balloon Delivery Catheter is an over-the-wire catheter offered in a two lumen catheter shaft design. One lumen is used to pass the catheter over a guidewire. The proposed device is designed to be placed over guidewires which have outer diameters of 0.035" or smaller. This lumen can also be used for infusion of contrast medium.

The second lumen communicates with the balloon and is used to inflate and deflate the balloon during the stenting procedure. The guidewire lumen and the balloon lumen terminate at the proximal end of the catheter by means of a bifurcated hub with luer lock fittings.

5.4 Intended Use

The Express™ Biliary LD Premounted Stent System is indicated for the treatment of biliary strictures produced by malignant neoplasms.

5.5 Summary of Technological Characteristics

The Boston Scientific Express Biliary LD Premounted Stent System will incorporate a substantially equivalent design, method of deployment, packaging, fundamental technology, manufacturing, sterilization and intended use as those featured in the

predicate Johnson and Johnson legally marketed Corinthian IQ Biliary Stent and Delivery System.

5.6 Non-clinical Test Summary

Functional testing for the stent component consisted of tensile and elongation, bile corrosion resistance, dimensional verification (strut widths, stent lengths), foreshortening, recoil, expansion uniformity, compression resistance, over expansion, and deployment accuracy.

Functional testing for the balloon delivery catheter consisted of multiple balloon inflation within a stent, balloon burst within a stent, balloon inflation and deflation time, balloon proximal bond tensile, stent / balloon crossing profile, sheath insertion / withdrawal force, stent securement force, tracking, and hub to shaft tensile.

Biocompatibility has also been conducted. Test results verified that the Express Biliary LD Premounted Stent System is adequate for its intended use and is considered substantially equivalent to the legally marketed Johnson & Johnson Corinthian IQ Transhepatic Biliary Stent with Delivery Catheter based on a comparison of intended use, the design, and the results of *in-vitro* testing and evaluation.

Product shelf life testing will be conducted and the data must show acceptable results after 2 years accelerated aging in order to claim the labeled shelf life of two years.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2002

Mr. Todd Kornmann
Senior Regulatory Affairs Specialist
Boston Scientific Scimed, Inc.
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K021630
Trade/Device Name: Boston Scientific Express™ Biliary LD Premounted Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: August 19, 2002
Received: August 22, 2002

Dear Mr. Kornmann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021630

Device Name: Boston Scientific Express™ Biliary LD Premounted Stent System

FDA's Statement of the Indications For Use for device:

The Boston Scientific Express™ Biliary LD Premounted Stent System is intended for the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021630